

INTERNATIONAL SEARCH REPORT

International Application No

PCT/US 03/34655

A. CLASSIFICATION OF SUBJECT MATTER

IPC 7 C07D207/12 A61K31/40 A61P9/06

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 C07D A61K

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the International search (name of data base and, where practical, search terms used)

EPO-Internal, BEILSTEIN Data, WPI Data, PAJ, CHEM ABS Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 99/50225 A (NORTRAN PHARMACEUTICALS INC) 7 October 1999 (1999-10-07) cited in the application page 6, line 16 - page 7, line 15; claims 1,5,8,10-15; examples 6,24	1-36, 51-83
E	WO 03/105756 A (FARHAN EMILE ; JURAYI JURJUS F (US); JOHNSON MATTHEY PHARMACEUTICAL (U) 24 December 2003 (2003-12-24) abstract page 14, line 22 - page 15, line 8; claims; examples	1-100

☐ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

* Special categories of cited documents :

- *A* document defining the general state of the art which is not considered to be of particular relevance
- *E* earlier document but published on or after the international filing date
- *L* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- *O* document referring to an oral disclosure, use, exhibition or other means
- *P* document published prior to the international filing date but later than the priority date claimed

- *T* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- *X* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- *Y* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.
- *&* document member of the same patent family

Date of the actual completion of the international search

30 June 2004

Date of mailing of the international search report

12/07/2004

Name and mailing address of the ISA

European Patent Office, P.B. 5818 Patentlaan 2
NL - 2280 HV Rijswijk
Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,
Fax: (+31-70) 340-3016

Authorized officer

Hanisch, I

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 03/34655

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.: 1, 5, 7, 9, 13, 15, 17, 21, 23, 25, 29, 31, 33, 37, 39, 51-83(all part)
because they relate to subject matter not required to be searched by this Authority, namely:
Although claims 53, 55, 57-67, 69, 70, 72-84, 86, 87, 89-100 are directed to a method of treatment of the human/animal body, the search has been carried out and based on the alleged effects of the compound/composition.
2. ☒ Claims Nos.: 1, 5, 7, 9, 13, 15, 17, 21, 23, 25, 29, 31, 33, 37, 39, 51-83(all part)
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
see FURTHER INFORMATION sheet PCT/ISA/210
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this International application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
- ☐ No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Continuation of Box I.1

Although claims 53,55,57-67,69,70,72-84,86,87,89-100 are directed to a method of treatment of the human/animal body, the search has been carried out and based on the alleged effects of the compound/composition.

Continuation of Box I.1

Claims Nos.: 1,5,7,9,13,15,17,21,23,25,29,31,33,37,39,51-83(all part)

Rule 39.1(iv) PCT - Method for treatment of the human or animal body by therapy

Continuation of Box I.2

Claims Nos.: 1,5,7,9,13,15,17,21,23,25,29,31,33,37,39,51-83(all part)

It is noted that the application refers to "metabolites", "metabolic precursors" and to "prodrugs". These are functional definitions which attempt to define a chemical compound in terms of a result to be achieved without a specific technical guidance for the selection of the suitable derivatives in the description and without proven general knowledge to show which derivatives are suitable metabolites, precursors thereof or prodrugs. These terms could be seen as a mere invitation to the skilled person to perform a research program in order to find the suitable variants. Page 108 only gives a non-limitative list of three possible chemical modifications of a parent drug to yield a prodrug. In such a situation, when the invention cannot be carried out over the whole claimed area without imposing an undue burden upon the skilled person, the disclosure may be considered insufficient, even when simple in vivo or in vitro tests are available to determine whether or not a particular compound is covered by the claims. Consequently, the search has been restricted by omitting the terms "metabolites", "metabolic precursors" and "prodrugs" in the claims.

The applicant's attention is drawn to the fact that claims relating to inventions in respect of which no international search report has been established need not be the subject of an international preliminary examination (Rule 66.1(e) PCT). The applicant is advised that the EPO policy when acting as an International Preliminary Examining Authority is normally not to carry out a preliminary examination on matter which has not been searched. This is the case irrespective of whether or not the claims are amended following receipt of the search report or during any Chapter II procedure. If the application proceeds into the regional phase before the EPO, the applicant is reminded that a search may be carried out during examination before the EPO (see EPO Guideline C-VI, 8.5), should the problems which led to the Article 17(2) declaration be

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

overcome.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/US 03/34655

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
WO 9950225	A	07-10-1999	AT 260240 T	15-03-2004
			AU 751772 B2	29-08-2002
			AU 3021599 A	18-10-1999
			BR 9909282 A	16-10-2001
			CA 2326777 A1	07-10-1999
			WO 9950225 A1	07-10-1999
			CN 1303364 T	11-07-2001
			DE 69915063 D1	01-04-2004
			EE 200000583 A	15-02-2002
			EP 1422217 A2	26-05-2004
			EP 1087934 A1	04-04-2001
			HU 0102613 A2	29-04-2002
			ID 27178 A	08-03-2001
			JP 2002509908 T	02-04-2002
			NO 20004897 A	13-11-2000
			NZ 507169 A	27-02-2004
			PL 343425 A1	13-08-2001
			SK 14372000 A3	10-07-2001
			TR 200002796 T2	21-12-2000
			ZA 200005195 A	27-06-2002
WO 03105756	A	24-12-2003	WO 03105756 A2	24-12-2003
			US 2004049049 A1	11-03-2004